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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/677,471	10/02/2003	Kevin P. Baker	10466/484	1021

7590 11/02/2004

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EXAMINER	
VOGEL, NANCY S	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 11/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/677,471	BAKER ET AL.	
	Examiner	Art Unit	
	Nancy T. Vogel	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 August 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-28 and 35-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-28 and 35-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 25-28 and 35-40 are pending in the instant application.

Those rejections which were present in the previous Office action mailed 5/4/04, but which do not appear in the present Office action, have been withdrawn.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Inventorship

In view of the papers filed 8/12/04, the inventorship in this nonprovisional application has been changed by the deletion of Kevin P. Baker, David Botstein, Dan L. Eaton, Napoleone Ferrara, Ellen Filvaroff, Mary E. Gerritsen, Kenneth Killan, Ivar J. Kljavin, Mary A. Napier, and Margaret Ann Roy.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of Office records to reflect the inventorship as corrected.

Claim Objections

Claim 35 is objected to because of the following informalities: part (c) contains an unmatched bracket, which presumably is a typographical error. Appropriate correction is required.

Claim Rejections - 35 USC § 101

Claims 25-28 and 35-40 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

This rejection on is maintained for the reasons made of record set forth in the previous Office action, mailed 5/4/04.

Applicants' arguments, and the declaration of Dr. Sherman Fong submitted therewith, of 8/10/04, have been considered but have not been found convincing.

Applicants have argued that since the specification discloses that the polypeptide encoded by the nucleic acids of the claims is "capable of inhibiting T-cell proliferation", this is adequate support for a "specific utility", and further, that they have disclosed a condition to be treated by the sequence of the instant application, i.e. "the immune response". Applicants further argue that one of ordinary skill in the art would "appreciate that only certain diseases involve treatment of the immune response", and present the Declaration of Sherman Fong, Ph.D. in support of this argument. Applicants further argue that Dr. Fong states that the MLR assay of the present invention identifies immune stimulants that can boost the immune system to respond to a particular antigen" and further, "the MLR assay is not a general predictor of immune response but rather is a specific assay designed to test the ability of a sample, such as an isolated nucleic acid encoding the polypeptide of SEQ ID NO:83 or an isolated nucleic acid of SEQ ID NO:82, to inhibit the drive of dendritic cells to induce T-cell proliferation" (page 6). However, these general statements fail to address the main contention of the

previous Office action, which is that there is a poor correlation between in vitro results and in vivo results using the MLR assay. Applicants' further arguments regarding this matter at pages 6-8 are not found convincing, since applicants set forth several examples of particular test substances in the MLR, which correlated to in vivo results. While in these instances there may have been a correlation, it is maintained that the general teachings in the art, as evidenced by the art previously cited in the Office action of 5/4/04, show that such a correlation is not generally accepted. One of ordinary skill in the art, in possession of these general teachings would recognize that one cannot extrapolate the utility of a compound for suppressing any particular immune response in vivo, from the MLR in vitro assay. Applicants also argue that one of ordinary skill in the art would "appreciate that CD4-IgG is an antibody that might be used as a negative control by blocking or preventing activation of allogeneic responder cells" (page 9) and further, that "applicants disclose that cell culture media can be used as a control" (page 9), fails to address the issues raised in the previous Office action, namely, there are several controls which would be meaningful for this assay, including autologous controls, a control to determine maximum response, screening for possible HLA antibodies and growth support capabilities, and internal controls. These issues have not been addressed. Furthermore, the issue of lack of statistical analysis, or the lack of the presence of the data itself, provides further uncertainty in the evaluation of any in vitro effect of the PRO361. For the reasons set forth above, applicant's arguments have not been found convincing, and the rejection is maintained.

Claim Rejections - 35 USC § 112

Claims 25-28 and 35-40 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

This rejection is maintained for the reasons set forth above.

The following is a new rejection necessitated by Applicant's amendments:

Claim 40 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claimed invention employs novel biological materials, specifically the cDNA deposited under ATCC accession number 20961. Since the biological material is essential to the claimed invention it must be obtainable by a repeatable method set forth in the specification or otherwise readily available to the public. If the biological material is not so obtainable or available, the requirements of 35 USC 112 may be satisfied by a deposit of the biological material. The specification does not disclose a repeatable process to obtain the biological material and it is not apparent if the biological material is readily available to the public. It is noted that Applicant has deposited the biological material, but there is no indication in the specification as to public availability. IF the deposit is made under the Budapest Treaty, then an affidavit or declaration by

Applicant, or a statement by an attorney of record over his or her signature and registration number, stating that the specific biological materials have been deposited under the Budapest Treaty and that the biological materials will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement mad here. If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809, Applicant may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent whichever is longer;

(d) the test of the viability of the biological material at the time of deposit will be made (see 37 C.F.R. 1.807); an

(e) the deposit will be replaced if it should ever become inviable.

Applicant's attention is directed o MPEP 2400 in general, and specifically to 2411.05, as well as to 37 CFR 1.809(d), wherein it is set forth that "the specification shall contain the accession number for the deposit, the date of the deposit, the name and address of the depository, and a description of the deposited material sufficient to

specifically identify it and to permit examination." The specification should be amended to include this information, however, Applicant is cautioned to avoid the entry of new matter into the specification by adding any other information. Finally, Applicant is advised that the address for the ATCC has recently changed, and that the new address should appear in the specification. The new address is:

American Type Culture Collection

10801 University Boulevard

Manassas, VA 20110-2209

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy T. Vogel whose telephone number is (571) 272-0780. The examiner can normally be reached on 6:30 - 3:00, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nancy T. Vogel
10/28/04

JAMES KETTER
PRIMARY EXAMINER